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| 10/682,310 | 10/08/2003 | Mattias Karlsson | 58282 (47137) | 7321 |

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| EXAMINER |
|---|
| PRICE, CRAIG JAMES |

| ART UNIT | PAPER NUMBER |
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| 3753 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/682,310 | KARLSSON ET AL. | |
| | Examiner | Art Unit | |
| | Craig Price | 3753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28-47* is/are pending in the application.

4a) Of the above claim(s) *1-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 March 2007 has been entered.

### *Oath/Declaration*

2. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Rather the filed oath states that,

"I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a). "

Please resubmit a new oath in accordance with 37 C.F.R. 1.56.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "an industry standard microtiter plate" is unclear. What plate does this cover? Is there a specification number for this standard which would better describe the plate? Please clarify.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (US 2002/0151078).

Kellogg et al. disclose a macroscale device, which is interfaced with a microscale device at an interface using double-sided tape (Para.0135,0138).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28-33 and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (6,536,477). Since anticipation is not based on probabilities or possibilities, these claims have been rejected based on obviousness.

O'Connor et al. disclose that a macroscale device which is interfaced with a microscale device at an interface using double-sided tape, and a macroscale device which is interfaced with a microscale device at an interface using transfer tape (Col.3, Lns. 60-67 and in Col.6, Lns.39-42, the pumping device is considered as a macroscale device).

Regarding claim 30, O'Connor et al. disclose that the microscale device is a microfluidic device (Col.2, Lns. 3-5).

Regarding claims 31 and 39, O'Connor et al. disclose that the microscale device is a MEMS device (Col.6, Lns.39-50).

Regarding claims 32 and 33, O'Connor et al. disclose that the microfluidic device comprises at least one microchannel and that the microfluidic device comprises a plurality of microchannels as shown.

Regarding claim 36, O'Connor et al. disclose that the microfluidic device further comprises one or more sensor chambers (the microfluidic modules) for containing one or more sensors.

Regarding claim 37, O'Connor et al. disclose that the one or more sensor chambers is for containing one or more cells (Col.6, Lns. 2-4).

Regarding claim 38, O'Connor et al. disclose that the microfluidic device comprises at least one electrical element (141 and Col. 9, Lns. 13-45) for performing planar patch clamp analysis. The limitation "for performing…" is considered as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 40, O'Connor et al. disclose that the macroscale device comprises a pump head connectable to a pressurized air supply (Col. 7, Lns. 54-56 disclose that the air channel is compressed therefore there must be some opening

which lets the air in, therefore this opening would be considered a head which is connectable to pressurized air supply).

Regarding claim 41, O'Connor disclose that the macroscale surface interfaced with a microscale surface is a surface of a device being a pump (Col. 6, Lns. 39-42) thereby being selected from the group consisting of a pump head, pump, degasser, flow meter, injector manifold, a pressure sensor; flow cell; concentration manifold or cartridges; a fitting or connector, a mixer, a compressor, an ultrasonic bed, an extractor, a focusing device, a dialysis chamber, an absorption chamber, a metabolite chamber, a toxicity chamber, a cell chamber, a detector, an RFID tag, a reagent vessel, a separation column, a focusing column, a size exclusion column, an ion-exchange columns; affinity columns; solid-phase extraction beds; a filter; a sieve; a frit; a depth filter, a heater, a heat exchanger, a cooler; a magnetic field generator; electric field generator; electroporation device, patch clamp pipette, and one or more connections thereto.

Regarding claim 42, O'Connor et al. disclose that the detector is a fluorescence flow cell (Col. 5, Lns. 56-58) which is selected from the group consisting of a UV/Visible absorbance flow cell, a fluorescence flow cell, a conductivity flow cell, an electrochemical detector, a plasma detector, surface plasmon resonance detector and a mass spectrometry detector.

Regarding claim 43, O'Connor et al. disclose that the detector is an optical sensor such as disclosed in Column 6, lines 42-47, selected from the group consisting of a flow meter, a pressure transducer, a temperature sensor, a chemical sensor, an

acoustic sensor, a color sensor, an optical sensor, a bar code sensor, a photothermal sensor, a photoacoustic sensor, and an RFID tag.

7. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al '477 in view of Pfost (5,104,621).

O'Connor et al. disclose all of the features of the claimed invention although is silent to a system, wherein the microchannels correspond in number to the number of wells in an industry-standard microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the industry-standard microtiter plate.

Pfost et al. disclose an analytical automated chemistry processing center which teaches the use of a microtiter plate (Col. 11, Lns. 45-48).

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the microtiter plates of Pfost et al. into the system of O'Connor et al. to have a system wherein the microchannels correspond in number to the number of wells in an industry-standard microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the industry-standard microtiter plate, in order to have an automated material handling system which could transfer the samples from one well of one microtiter plate to a different well in another microtiter plate depending on the type of analysis desired (Col. 11, Lns. 45-53).

8. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (6,536,477) in view of Crandall et al. (6,352,766).

O'Connor et al. have disclosed all of the features of the claimed invention although is silent to the system having at least one adhesive side of the tape surface is covered by a release liner prior to adhering the device surface of the macroscale or microscale device and adhesives on each side of the double sided tape comprise different types of adhesive.

Crandall et al. disclose a low adhesion material which teaches a device as having at least one adhesive side of the tape surface is covered by a release liner (Col. 5, Lns. 38-41) prior to adhering the device surface of the macroscale or microscale device and adhesives on each side of the double sided tape comprise different types of adhesive (Col. 5, Lns. 41-45).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ the system having at least one adhesive side of the tape surface is covered by a release liner prior to adhering the device surface of the macroscale or microscale device and adhesives on each side of the double sided tape comprise different types of adhesive of Crandall et al. onto the device of O'Connor et al. in order to permit the easy removal of the liner from the coated article (Col.1, Lns 21-30).

9. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (6,536,477) in view of DiZio et al. (6,455,152).

O'Connor et al. have disclosed all of the features of the claimed invention although is silent to the system having the adhesive on the tape is patterned onto a

backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive.

Dizio et al. disclose an adhesive coating article which teaches the use of the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive (Col. 5, Lns. 39-41).

It would have been obvious ot one of ordinary skill in the art at the time of invention to utilize the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive of Dizio et al. onto the system of O'Connor et al. in order to reduce the surface contact between the transfer surface and the adhesive (Col. 5, Lns. 9-20) to have a better transfer of adhesive during the manufacturing process when joining the micro and macroscale devices.

## *Response to Arguments*

10. Applicant's arguments with respect to claims 28-47 have been considered but are moot in view of the new ground(s) of rejection.

## *Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig Price whose telephone number is (571) 272-2712. The examiner can normally be reached on 7AM - 5:30PM M-R, Increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Keasel can be reached on (571) 272-4929. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CP/ 29 May 2007

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